each of the last three years and the names of parties who imported the drug during the same period;

(b) what is the indication for which this drug was cleared for marketing and the names of five leading brands under which the drug is being marketed in the country;

(c) whether it is a fact that his Ministry has treated this drug to be non-essential;

(d) if so, what is the criteria adopted by his Ministry;

(e) whether it is also a fact that his Ministry has prepared a list of non-essential drugs; and

(f) if so, what are the names of those drugs?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Information available with this Miinstry regarding import of Amitriptyline during the years 1985-86, 1986-87 and 1987-88 is given in the enclosed statement (*See* below)

(b) Amitriptyline is used for management of depression. Five popular brand names are Amiline, Amitrol, Quietal, Tryptamol and Tripetel.

(c) to (f) Ministry of Health and Family Welfare has not made any list of non-essential drugs nor has it labelled any drug non-essential.

Statement

Year	Quantity in kgs.	Average C.I.F. price per kg.
1985-86 . . .	2,185	956.85
1986-87 . . .	2,600	933.00
1987-88 .	3,061	845.15

Adoption of good manufacturing practice by Drug Companies

737. SHRI DHARANIDHAR BASUMATARI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that good manufacturing practice has been made obligatory for the drug manufacturing companies;

(b) if so, since when;

(c) what steps have been taken to get this implemented and by when all the units will adopt GMP;

(d) whether it is a fact that Government have made a policy to give 10 per cent extra conversion cost to Units which are found adopting GMP;

(e) whether it is also a fact that all small scale units, irrespective of annual turn over, are exempted from price control, and that high percentage of medicines are out of price control;

(f) if so, what is the purpose of such incentive and on what basis such incentive has been announced; and

(g) by when all the units would be inspected from the GMP angle?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) Good Manufacturing Practices have been made obligatory vide Gazette Notification CSR No. 735 (H), dated 24-6-88. As per this notification these rules shall come into force on the date of their publication in Official Gazette i.e. 24-6-1988. All State Drugs Controllers have been advised to ensure implementation of these rules.

(d) to (f) An Order bearing S.O. No. 130(E), dated 17th February 1989, *inter alia* provides that the Government may grant extra conversion cost at the rate of 10 per cent of the above norms to a manufacturer having manufacturing practices more than the standards prescribed under Drugs and Cosmetics Act, 1940 and the rules made there under and under

any other statutory requirements for the time being in force for the production of quality drugs, as per the procedure laid down therein. Since the exact criterion is yet to be finalised by the Government, the Scheme has not yet been implemented.

Since the formulations falling in Category II of the drugs Prices Control Order, 1987 and produced by the Small Scale Sector Units are exempt from price control subject to certain conditions, obviously, they are not *ab-initio* eligible for the aforesaid incentive for Category II formulations.

(g) All the State Drugs Controllers have been advised to ensure that every manufacturer compiles with the rules incorporating provisions of Good Manufacturing Practices. Under the provisions of Drugs and Cosmetics Rules every manufacturing unit should be inspected atleast twice a year.

Flooding of markets with substandard vaccines

738. SHRI ASHOK NATH VERMA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the markets in the country are flooded with substandard vaccines;

(b) what are the number of samples drawn from the market of Polio Vaccine, Triple Antigen, Diphtheria Antitoxin and Toxid, Tetanus Antitoxin and Toxoid, Measles Vaccines, MMR Vaccines, Hepatitis Vaccine, Gammaglobuline, Anti-D Rho Gam and Rabbies Vaccines during the last three years, yearwise for testing;

(c) the number of each vaccines found to be of standard quality and what was the number of substandard vaccines;

(d) the names of the Laboratories where each vaccine was tested and what was the detailed report of each;

(e) whether his Ministry has taken any action against the producers, whose vaccines have found to be of sub-standard quality; and

(f) if so, the action taken in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) No, Sir.

(b) to (d) Under the provisions of the Drugs & Cosmetics Rules the Central Research Institute, Kasauli Institute, Kasauli has been notified as the statutory laboratory for testing of all Human, Sera and Vaccines. The statement showing the details of samples of vaccines tested during 1988 as received from the Central Research Institute, Kasauli as available with this Ministry is attached as Annexure [*See* Appendix CL, Annexure No. 37].

(e) and (f) Under the provisions of the Drugs & Cosmetics Rules the State Drugs Controllers take necessary action like withdrawal of batches from market, cancellation|suspension of Mfg. Licence or to prosecute depending upon the case against the manufacturer whose sample has been found sub-standard.

Essentiality of Trifluoperazine

739. SHRI ASHOK NATH VERMA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Kelkar Committee has sought advice in respect to the essentiality of Trifluoperazine;

(b) if so, when;

(c) whether his Ministry has prepared a list of essential drugs and Trifluoperazine does not fall under that list;

(d) if so, what are the names of drugs covered under essential list;

(e) whether it is a fact that Trifluoperazine is being imported in the country;